Rec'd PCT/PTO 28 APR 2005

PCT/GB2003/004692
10/533009
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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference

01NOV02 E760240-1 002059
P01/7700 0.00-0225427.4

2. Patent application number
(The Patent Office will fill in this part)

0225427.4

01 NOV 2002

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Dr. Mirza Kamran Baig
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Nottingham NG7 2GZ

Patents ADP number *(if you know it)*

8497182001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

STENT RETRIEVAL DEVICE

5. Name of your agent *(if you have one)*

Sanderson & Co.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including postcode)*

34 East Stockwell Street
Colchester
Essex
CO1 1ST

Patents ADP number *(if you know it)*

1446001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.

See note (d))

No

Figure 1

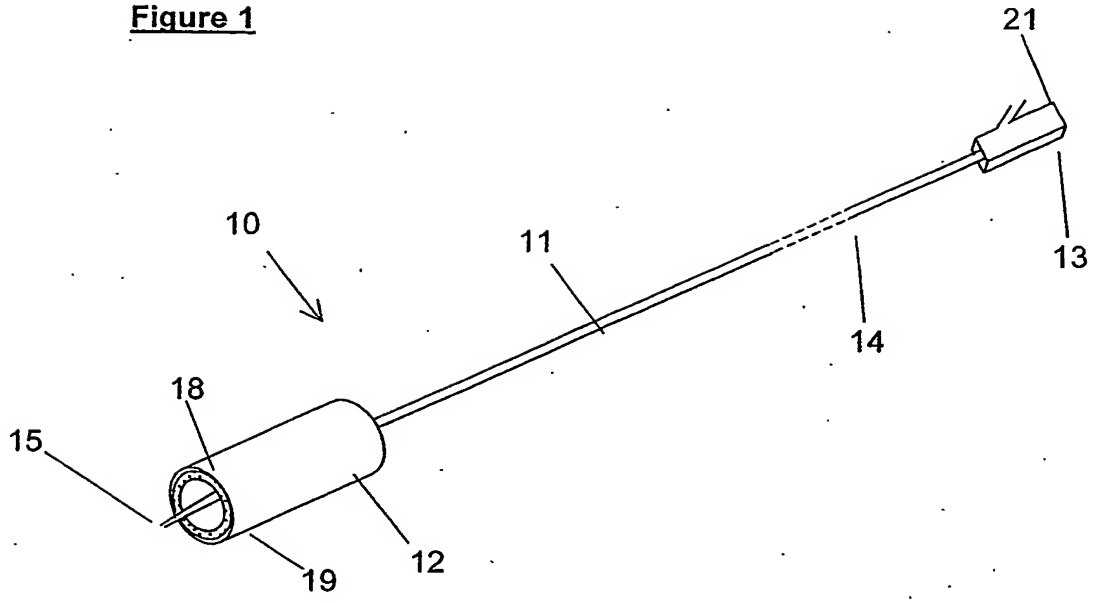


Figure 2

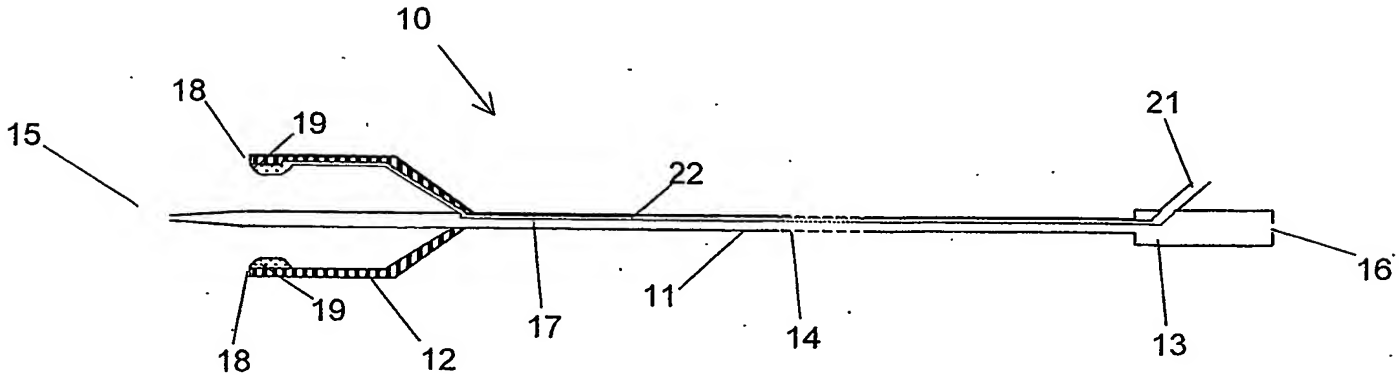


Figure 3

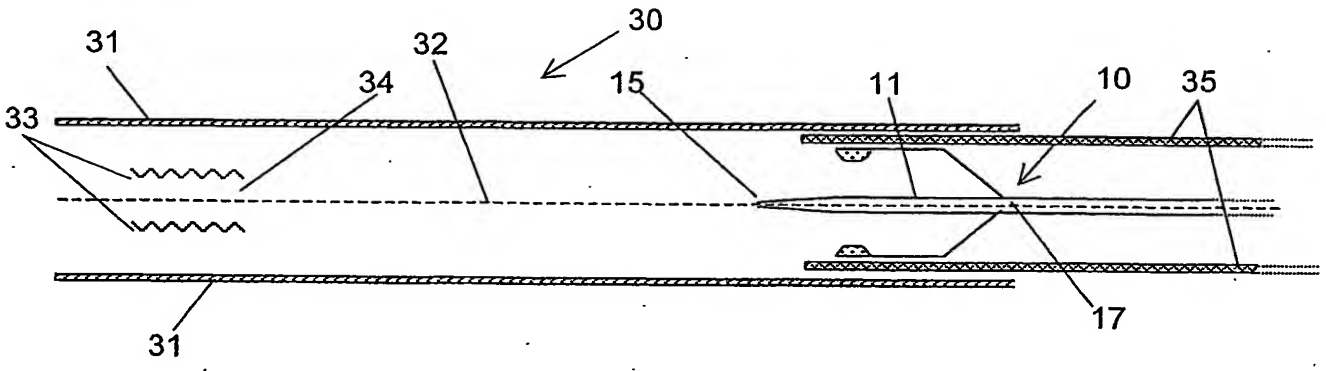


Figure 4

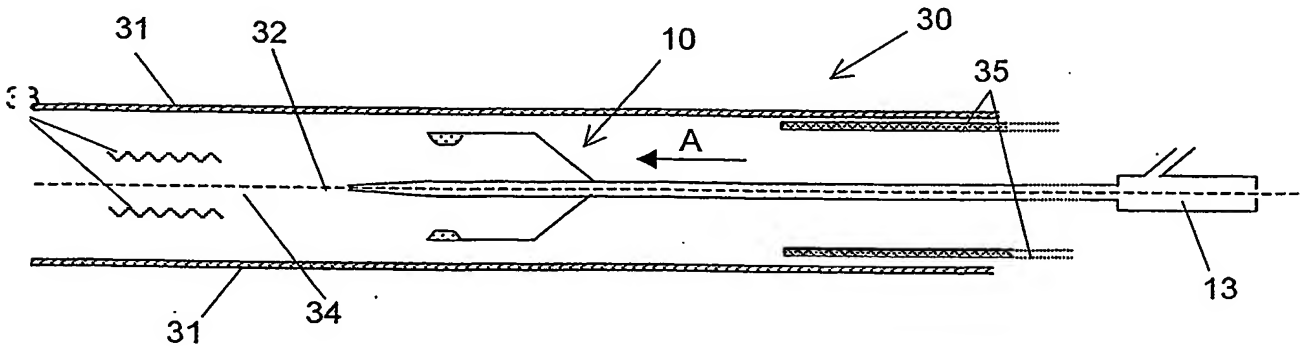


Figure 5

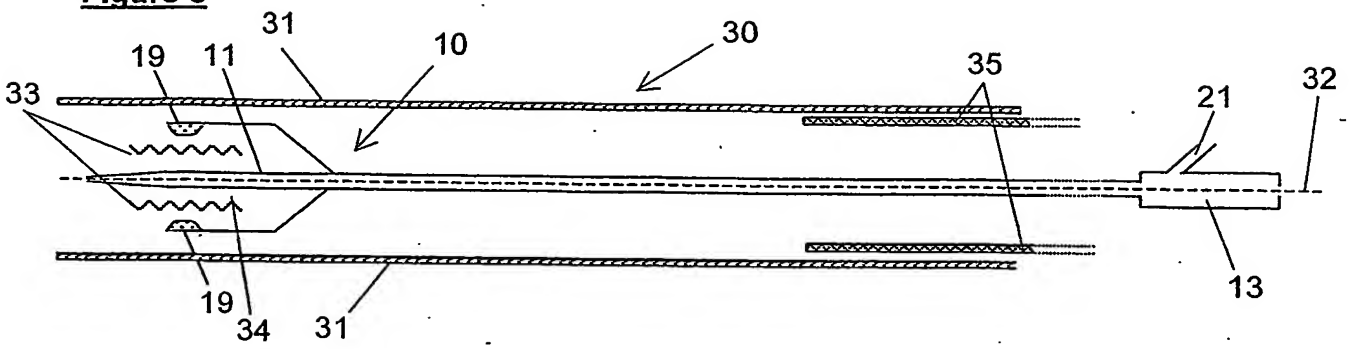


Figure 6

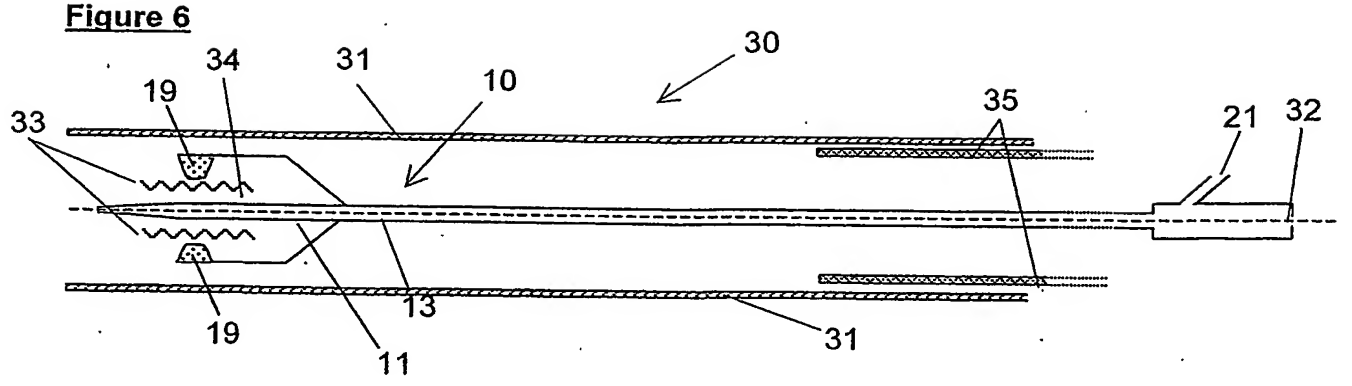


Figure 7

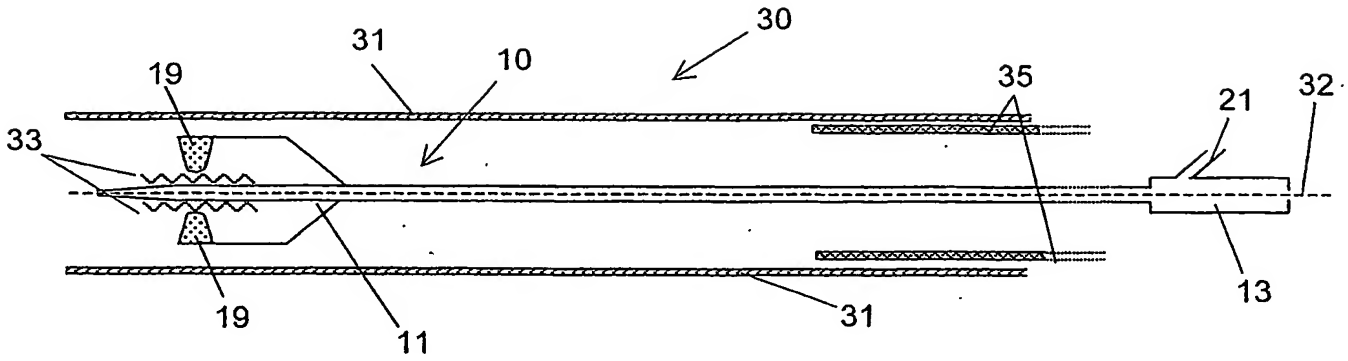


Figure 8

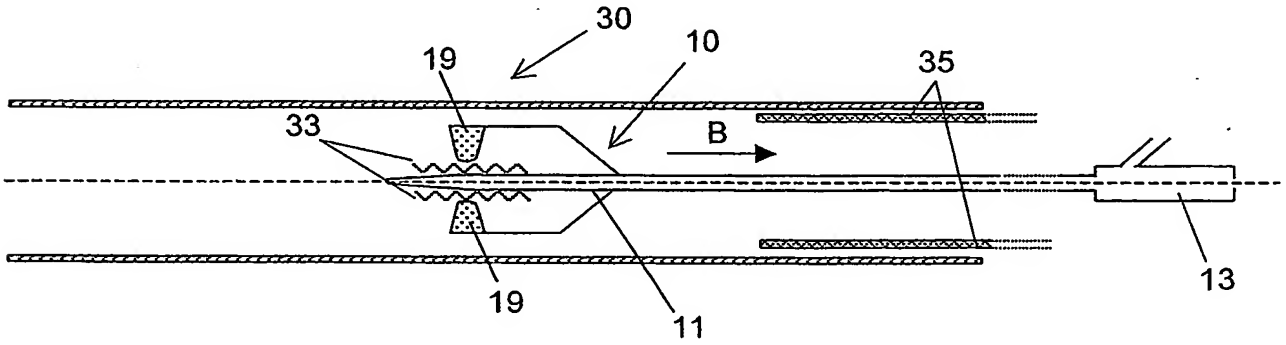
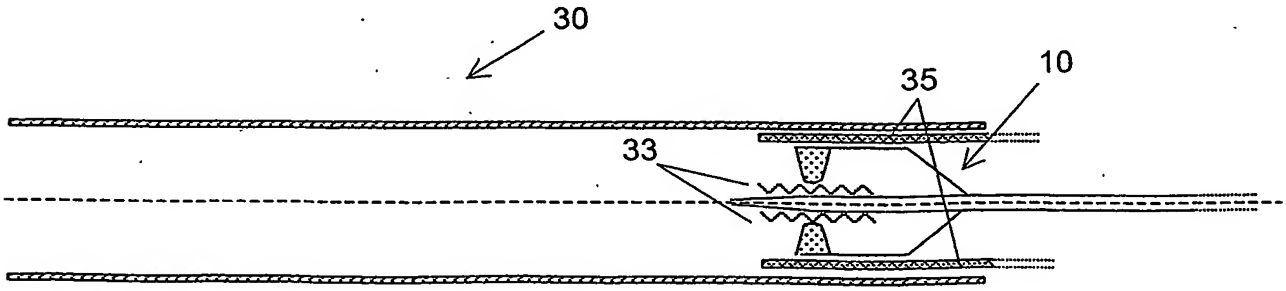


Figure 9



Stent Retrieval Device

This invention relates to a device for the retrieval of an undeployed stent from a vessel of a patient during an intravascular angioplasty procedure.

Intravascular angioplasty is a surgical procedure for the repair of a collapsed or constricted blood vessel. A standard technique is to introduce a balloon-tipped catheter into the vessel, usually along a previously placed guidewire. Once the balloon tip of the catheter has been located at the site of the stricture, or stenosis, it is then inflated thereby dilating the vessel and hence improving blood flow. It is common to treat any residual stenosis in the vessel by placing a stent, usually a perforated metal tube, into the vessel to provide radial support to the vessel wall.

The stent is usually introduced in a compressed, or "undeployed" condition, carried on the deflated balloon of a balloon-tipped catheter. The balloon, which is positioned within the central cavity of the stent, is then inflated so as to expand, or "deploy" the stent at the required site.

However, a problem sometimes encountered with this procedure is that the undeployed stent can become detached from the delivery balloon, and thus becomes a free-floating foreign body within the vessel. Not only can this impede blood flow, and thus cause the vessel to occlude, but also presents the more serious hazard of the stent embolising (floating off) to another part of the body. If the embolised stent should reach a vital organ, the consequences can be

dire – for example, a stroke can occur if an embolised stent reaches the brain.

Furthermore, one of the most significant applications of intravascular angioplasty is in the repair of the coronary artery, without the need for open surgery. If an undeployed stent should become detached from its delivery balloon during a coronary angioplasty procedure, it is often necessary to proceed immediately to open surgery in order to remove the stent.

Despite the critical nature of this problem, current techniques for retrieving undeployed stents from a vessel are generally inadequate, and often the only way to ensure retrieval of the stent is by open surgery. Such standard techniques include providing miniature forceps or a so-called "goose neck" snare device at the tip of a catheter, to attempt direct grasping of the stent.

The use of balloon-tipped catheters for retrieval, as well as delivery of stents has also been proposed. However, devices based on this principle tend to require the user to "thread" the deflated balloon back into the central cavity of the undeployed stent, and then to re-inflate it once in position. Such devices are rather awkward to use, and frequently result in the stent being pushed further into the vessel, or deployed at an unintended location in the vessel.

It has now been realised that a solution to this problem is achievable by providing a device having a balloon arranged when inflated to bear against the outer, rather than the inner, circumference of the stent. However, in order to ensure that the captured stent does

not become detached from the retrieval device before the device as a whole is withdrawn from the vessel, the device must also have a central component arranged to pass through the cylindrical central cavity of the stent, in order that the inflated balloon can urge the stent thereagainst.

Therefore, according to the present invention there is provided a device for retrieval of an undeployed stent from a vessel of a patient, which device comprises: a flexibly resilient central shaft having an axial channel for receiving an angioplasty guidewire therein; balloon support means extending from the central shaft and having a free end spaced therefrom; and inflatable balloon means provided at said free end and arranged to expand inwardly towards the central shaft upon inflation; whereby in use the device is positioned such that an undeployed stent is located between said free end and said central shaft, and the balloon means is subsequently inflated to bear against the outer circumference of the stent and hold it against the central shaft, such that the combined stent and device can be withdrawn from the vessel.

It will be appreciated that the inflatable balloon means must be arranged so as in use to bear against the stent in at least two locations around its circumference, so that the stent is grasped by the balloon means on inflation. For example, this may be achieved by the provision of two or more separate balloon means carried on the free end of two or more balloon support means at spaced intervals around the central shaft. However, it is preferred that there should be only

one inflatable balloon means, having a generally annular shape, such that on inflation the balloon means bears against the entire outer circumference of the stent.

Similarly, while the balloon support means might feasibly comprise two or more elements arranged at spaced intervals around the central shaft, it is preferred that the balloon support means should take the form of a generally cylindrical tube or sleeve, surrounding the central shaft and extending generally axially relative thereto.

The free end of the balloon support means thus takes the form of a rim of the tube or sleeve, said rim being generally circular and having the central shaft passing through its centre. In embodiments where the balloon support means is other than a tube or sleeve, it is nevertheless preferred that the free end should be a rim. In embodiments where the balloon support means comprise one or more separate elements, it is preferred that the free ends of those elements should be one or more rim members defining a notional rim around the central shaft.

The central shaft is preferably of a generally cylindrical construction, having a uniform diameter along most of its length, but with a short tapering portion towards its tip. The diameter of the shaft should be as small as is practicable, in order that it can be fed into the cylindrical central cavity of the stent. In preferred embodiments, the tip extends beyond the free end of the balloon support means.

The device preferably has a hub at the end of the central shaft distal from the sleeve, the mouth of the sleeve being directed away

from the hub. A port is provided on the hub, which is in fluid communication with the balloon, preferably by means of an inflation tube passing along the axial channel in the central shaft and into the balloon support means. Inflation of the balloon may therefore be effected by the injection of an inflation fluid through the port.

The port is preferably adapted to receive a syringe from which substantially 2 to 5 ml of inflation fluid can be injected to inflate the balloon. In order that the progress of the surgical procedure may be followed by standard radiographic techniques, it is much preferred that the inflation fluid is of radiographic contrast.

Once the device of the present invention has been used to capture a free-floating stent, it is desirable that the combined device and stent assembly should be capable of being withdrawn quickly and easily from the vessel of the patient. Consequently, it is preferred that the device should be adapted for delivery into and recovery from a vessel by means of a guiding catheter, which may be of a standard construction.

The guiding catheter will often already be in place, having been used previously for the introduction of the stent itself and other tools used in the angioplasty procedure. Similarly, the guiding catheter and the angioplasty guidewire will usually be retained in position following retrieval of the undeployed stent, in order to continue the angioplasty procedure.

In an alternative embodiment of the present invention, there is provided a kit of parts comprising a stent retrieval device as

hereinbefore described, and further comprising a guiding catheter for delivery of the device into a vessel, and subsequent recovery of the device therefrom.

In order that the present invention may be more clearly understood, a preferred embodiment will now be described in detail, though only by way of example, with reference to the following drawings, in which:

Figure 1 is a perspective view of a stent retrieval device according to the present invention;

Figure 2 is a cross-sectional side view of the stent retrieval device of Figure 1; and

Figures 3 to 9 are an illustrative sequence showing the stent retrieval device of Figures 1 and 2 being used to remove an undeployed stent from a vessel of a patient.

Referring first to Figures 1 and 2, there is shown a stent retrieval device according to the present invention, generally indicated 10. The device 10 comprises a flexibly resilient central shaft 11 having a generally cylindrical sleeve 12 at one end thereof, and a hub 13 at the other end thereof. The central shaft 11 will in practice be considerably longer than shown here, as indicated at 14. The shaft 11 is generally cylindrical along its length, and tapers towards a tip 15 having an aperture therein allowing access to a channel 17 running axially along the length of the shaft 11 A further aperture 16 is provided at the other end of the shaft 11, also in communication with the channel 17.

The sleeve 12 extends axially relative to the central shaft 11 and has a free end defining a circular rim 18 having the central shaft 11 at its centre. The tip 15 of the central shaft 11 extends beyond the rim 18. The rim 18 acts as a support means for a generally annular balloon 19 provided internally therearound, and arranged to expand inwardly towards the central shaft 11 on inflation. The balloon 19 communicates with an inflation port 21 located on the hub 13, by means of an inflation tube 22 extending along the channel 17 and into the sleeve 12.

Use of the device 10 in a surgical procedure will now be described with reference to Figures 3 to 9.

Referring first to Figure 3, there is shown a vessel of a patient generally indicated 30, defined by vessel walls 31. An angioplasty guidewire 32 extends generally axially along the vessel 30, having previously been located therein during an intravascular angioplasty procedure. A undeployed stent 33, which has become prematurely detached from its delivery catheter during the angioplasty procedure, is located in the vessel 30. The stent 33 has a central cavity 34 through which the guidewire 32 extends, but is otherwise free-floating within the vessel 30. Both the stent 33 and its central cavity 34 are generally cylindrical.

The stent retrieval device 10 is introduced into the vessel 30, by means of a guiding catheter 35. As with the guidewire 32, the guiding catheter 35 will usually have been placed in position in the vessel 30 during the preceding angioplasty procedure. The device 10 is

introduced through the catheter 35 such that the guidewire 32 passes through the aperture in the tip 15 of the central shaft 11 and into the channel 17, such that the device 10 can be manoeuvred along the vessel 30 using the guidewire 32.

As can be seen from Figure 4, the catheter 35 is retained in position whilst the device 10 is driven out of the catheter 35, and further into the vessel 30 towards the stent 33, as indicated by arrow A. This is controlled by the surgeon from the hub 13 end of the device 10, which remains externally of the vessel 30, and indeed externally of the patient.

The device 10 is driven into the vessel 30 until the position shown in Figure 5 is reached, where the outer circumference of the stent 33 is surrounded by the generally annular balloon 19, and the tip 15 of the central shaft 11 protrudes through the central cavity 34 of the stent 33. Inflation of the balloon 19 is then initiated by the introduction of 2 to 5 ml of radiographic contrast inflation fluid, via the inflation port 21 located on the hub 13, and along the inflation tube.

As is shown in Figure 6, this causes the balloon 19 to expand inwardly toward the central shaft 11, until the balloon 19 bears against the outer circumference of the stent 33. Further inflation of the balloon 19, as shown in Figure 7, compresses the stent 33 so that it is held between the balloon 19 and the central shaft 11.

Referring now to Figure 8, the device 10, with the stent 33 grasped firmly between the balloon 19 and the central shaft 11, is then manoeuvred back toward the catheter 35, as indicated by arrow B. As

before, this motion is controlled by the surgeon, from the hub 13 end of the device 10, which has remained externally of the patient throughout the procedure. Finally, as shown in Figure 9, the combined stent 33 and device 10 assembly is withdrawn as one through the catheter 35, out of the vessel 30, and ultimately out of the patient. The catheter 35 and the guidewire 32 are usually left in position in the vessel 30, to enable subsequent angioplasty procedures.

CLAIMS

1. A device for retrieval of an undeployed stent from a vessel of a patient, which device comprises: a central shaft having an axial channel for receiving an angioplasty guidewire therein; balloon support means extending from the central shaft and having a free end spaced therefrom; and inflatable balloon means provided at said free end and arranged to expand inwardly towards the central shaft upon inflation; whereby in use the device is positioned such that an undeployed stent is located between said free end and said central shaft, and the balloon means is subsequently inflated to bear against the outer circumference of the stent and hold it against the central shaft, such that the combined stent and device can be withdrawn from the vessel.

2. A device as claimed in claim 1, wherein the central shaft is flexibly resilient and has a tip extending beyond the free end of the balloon support means.

3. A device as claimed in claim 1 or claim 2, wherein the inflatable balloon means is arranged so as in use to bear against the stent at two or more spaced locations around the circumference thereof.

4. A device as claimed in any of the preceding claims, wherein the inflatable balloon means is generally annular.

5. A device as claimed in any of the preceding claims, wherein the balloon support means is a generally cylindrical sleeve extending axially of the central shaft.

6. A device as claimed in any claims 2 to 5, wherein the central shaft is generally cylindrical, having a uniform diameter along most of its length, and a short tapering section towards its tip.

7. A device as claimed in any of the preceding claims, further comprising a hub at an end of the central shaft distal from the inflatable balloon means.

8. A device as claimed in claim 7 wherein the hub has a port in fluid communication with the balloon to enable inflation thereof by injection of an inflation fluid.

9 A device as claimed in claim 8 wherein the port is adapted to receive a syringe from which the inflation fluid is to be delivered.

10. A device as claimed in claim 8 or claim 9 wherein the inflation fluid is of radiographic contrast.

11. A device as claimed in any of claims 8 to 10, wherein the inflation of the balloon is effected by the injection of substantially 2 to 5 ml of inflation fluid.

12. A device as claimed in any of the preceding claims, said device being adapted for delivery into and recovery from a vessel by means of a guiding catheter.

13. A device as claimed in any of the preceding claims, further comprising a guiding catheter for delivery of the device into a vessel, and subsequent recovery of the device therefrom.

14. A device as claimed in claim 1, and substantially as herein described, and/or as shown in the accompanying drawings.